

इंटरनेट

मानक

Disclosure to Promote the Right To Information

Whereas the Parliament of India has set out to provide a practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, and whereas the attached publication of the Bureau of Indian Standards is of particular interest to the public, particularly disadvantaged communities and those engaged in the pursuit of education and knowledge, the attached public safety standard is made available to promote the timely dissemination of this information in an accurate manner to the public.

“जानने का अधिकार, जीने का अधिकार”

Mazdoor Kisan Shakti Sangathan

“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”

Jawaharlal Nehru

“Step Out From the Old to the New”

IS 7350 (1974): Needles, Spinal [MHD 1: Surgical Instruments]



“ज्ञान से एक नये भारत का निर्माण”

Satyanarayan Gangaram Pitroda

“Invent a New India Using Knowledge”



“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

BLANK PAGE



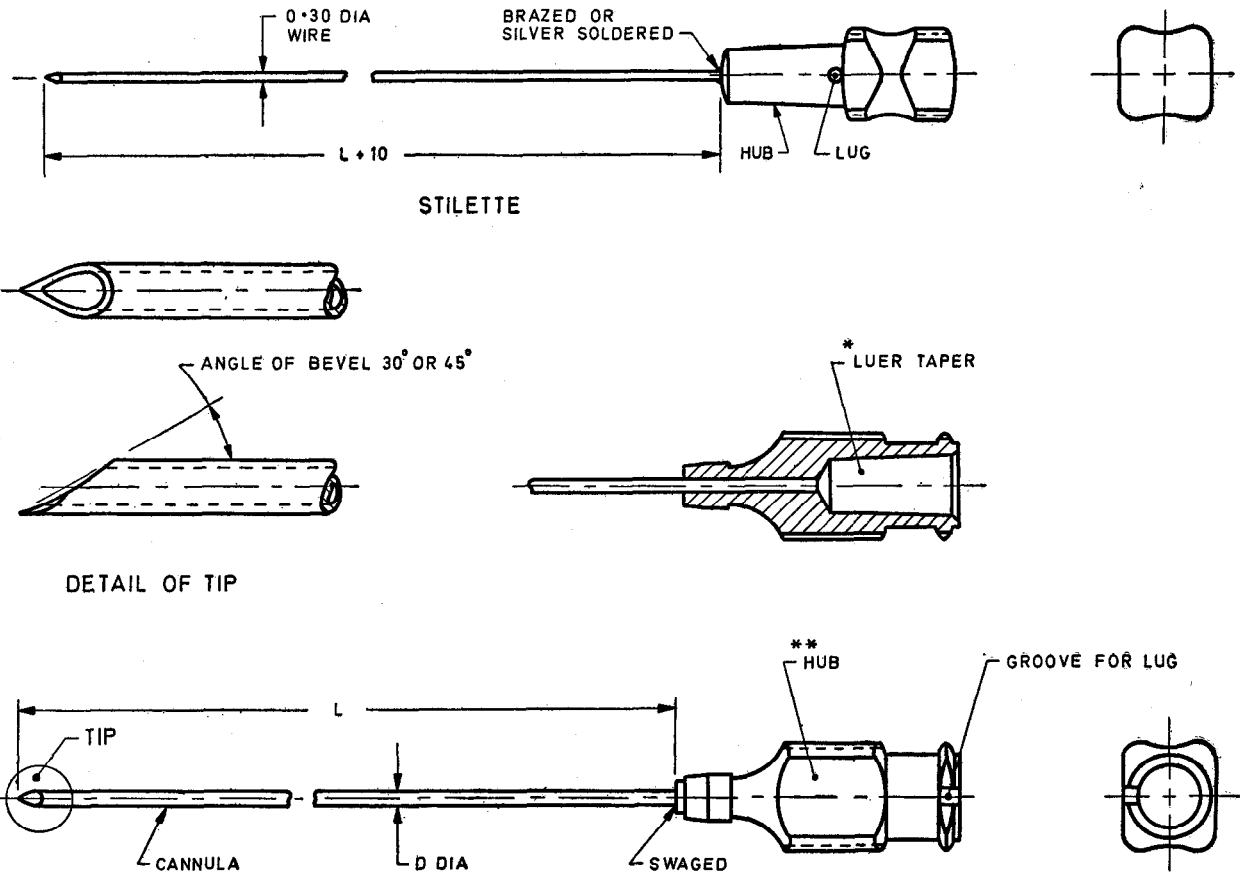
Surgical Instruments Sectional Committee, CPDC 11; Needles and Hollow Instruments Subcommittee, CPDC 11 : 2 [Ref : Doc : CPDC 11(802)]



Indian Standard
SPECIFICATION FOR
NEEDLES, SPINAL

(Reaffirmed 1998)

1. **Scope** — Specifies dimensional and other requirements of spinal needles.
2. **Shape and Dimensions** — As given in Fig. 1 and Table 1.



*See IS : 3234-1965 ' Specification for conical fitting for hypodermic syringes, needles and other medical equipment, Luer type '.

**See IS : 3317-1965 ' Specification for needles, hypodermic '.

All dimensions in millimetres.
FIG. 1 SPINAL NEEDLE

TABLE 1 SIZES OF SPINAL NEEDLES
(Clause 2, and Fig. 1)

All dimensions in millimetres.

Designation	Outside Diameter of Cannula, D	Length of Cannula, L		
		50	75	90
5	0.5	x	—	—
6	0.63	x	x	—
7	0.71	x	x	—
8	0.8	—	x	x
9	0.91	—	—	x
10	1.0	—	x	x
12	1.2	—	x	x
14	1.4	—	x	x
16	1.6	—	x	x

Note — 'x' indicates recommended diameter — length combinations.

Adopted 26 June 1974

© September 1974, ISI

Revised Print

3. Material

3.1 Cannula — The cannula shall be made from stainless steel drawn tubing. The stainless steel shall conform to designation 04Cr18Ni11, 07Cr18Ni9, 04Cr17Ni12Mo2 or 04Cr17Ni12Mo2Ti20 of IS : 1570 (Part V) - 1972 ' Schedules for wrought steels: Part V Stainless and heat-resisting steels (*first revision*) '.

3.2 Hub — The hub shall be made from free cutting brass rod or bar conforming to IS : 319-1968 ' Specification for free cutting brass rods and sections (*second revision*) '.

3.3 Stilette Wire — Stilette wire shall be hard drawn brass wire or stainless steel wire and supplied one for each needle.

4. Conical Fitting — The conical fitting shall be of the Luer type and shall be in accordance with IS : 3234-1965 ' Specification for conical fitting for hypodermic syringes, needles and other medical equipment, Luer type '.

5. Construction

5.1 The cannula shall be pushed well into the cavity of the hub but not extending into the conical portion and securely swaged. The cannula and the hub shall be concentric and well aligned.

5.2 Point of Needle — The needle point shall have a short bevel, 30° or 45° to axis. The point shall be sharpened on three aspects as shown in Fig. 1. It shall be sharp, well defined, free from any feather edge, irregularity and burrs when examined under 10 to 15 × magnification.

6. Finish

6.1 Cannula shall be smooth both outside and inside and free from pits, tool marks, burrs and foreign matter.

6.2 The hub shall be free from sharp edges and roughness. It shall be nickel or chromium plated, both inside and outside, and polished. The plating shall be such as to withstand the corrosion test given under 7.7.

6.3 Stilette wire shall be smooth, bright and free from foreign matter and shall slide smoothly into the cannula. The point of the needle shall coincide with point of the stilette. The stilette wire shall be brazed or silver soldered to a hub as shown in Fig. 1.

7. Tests

7.1 Leakage Test — Fit the needle to a tested syringe and connect the syringe to a source of water on which pressure could be exerted. Run the water through the needle to eliminate air, seal the needle point by piercing it into a piece of solid rubber and apply a pressure of 2.94 bar (3 kgf/cm² approx) for 10 seconds. No leakage shall take place at the joint of the hub and the syringe or the cannula and the hub.

7.2 Sharpness of Needle Point — Take an aluminium foil 0.02 mm thick and clean it with alcohol or benzene and mount suitably so that it is spread taut and the needle may penetrate vertically. Stand the needle with its point touching the foil ensuring that the weight of the needle did not act on foil. Apply load on the hub gently starting with one gram. Then increase the load gradually, so as to reach the test load in about 30 seconds. The needle shall penetrate the aluminium foil with a test load not exceeding 30 g.

7.3 Elasticity — Clamp the hub rigidly and deflect the cannula through an angle given in Table 2, force being applied at a contact distance as specified in Table 2. The needle shall show no permanent set or damage.

7.4 Reverse Bend Test — Clamp the hub firmly and apply force at points whose contact distance is in accordance with the requirements of Table 2, so that the cannula is deflected through the degrees specified, and reverse the test in the opposite direction. Perform the test for 20 complete cycles and examine the needle. The needle shall have suffered no damage and shall not have developed fracture.

7.5 Stiffness — Support the cannula of the needle at two places giving a span as shown in Table 2, and load it centrally as specified. The deflection of the cannula shall be not greater than the limits given in Table 2.

7.6 Security of Swaging — The swaging of the cannula with the hub shall be tested by applying for one minute a pull of magnitude given in Table 2. The cannula shall not come out of the hub and it shall not become loose.

TABLE 2 TESTS

(Clauses 7.3, 7.4, 7.5 and 7.6)

Diameter of Cannula	Elasticity		Reverse Bend Test		Stiffness			Security of Swaging, Pull to be Applied
	Contact Distance from Hub	Angle of Bend	Contact Distance from Hub	Deflection	Separation of Test Edges	Load	Deflection	
							Max	
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
mm	mm	Degrees	mm	Degrees	mm	g	mm	kg
0·5	16	12	16	25	12	700	13	2·5
0·63	16	12	16	25	15	1 100	16	3·5
0·71	16	12	16	25	15	1 100	16	3·5
0·8	19	12	19	25	15	1 400	16	4·5
0·91	25	12	25	25	25	1 700	16	5·5
1·0	29	12	29	25	25	2 000	25	6·5
1·2	32	12	32	25	25	2 000	25	6·5
1·4	32	9	—	—	25	2 200	25	9·0
1·6	32	9	—	—	25	2 200	25	9·0

7.7 Corrosion Resistance — The complete needle shall be immersed in a 10 percent solution of citric acid at room temperature for 5 hours. It shall then be boiled in distilled water for 30 minutes. The water and the immersed needle shall then be allowed to cool and shall remain at room temperature for 48 hours. The cannula or hub shall show no corrosion after having been dried by evaporation. The test shall be conducted in a glass container.

7.8 Freedom from Foreign Matter — The cannula and the hub shall be examined under good illumination with a magnifying lens; they shall be free from foreign matter, metal particles or chips, pits, burrs and other defects.

8. Marking — The hub of the needle shall be marked with the designation of the needle and the manufacturer's identification mark.

8.1 ISI Certification Marking — Details available with the Indian Standards Institution.

9. Packing — Needles shall be packed in accordance with the best trade practices and supplied with equal number of stilettes also packed suitably. The packet shall be marked with manufacturer's name and the purpose for which the needle is to be used.

AMENDMENT NO. 1 APRIL 1978
TO
IS:7350-1974 SPECIFICATION FOR
NEEDLES, SPINAL

Addendum

(Page 1, Fig. 1) - Add the following
note above the caption of the figure:

'Note - A deviation of $\pm 2^\circ$ shall be
permitted on angle of tip bevel.'

(CPDC 11)

Reprography Unit, ISI, New Delhi